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Sheet 1 of 1

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| Application Number | 10/725,009 |
| Filing Date | December 2, 2003 |
| First Named Inventor | GEALL, Andrew |
| Art Unit | 1645 |
| Examiner Name | HINES, Jana A. |
| Attorney Docket Number | 1530.0620001/EJH/UWJ |

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

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| Examiner Signature | /Jana Hines/ (05/26/2008) | Date Considered | 05/26/2008 |
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| Sheet | 1 | of | 3 | Attorney Docket Number | 1530.0620001/EJH/UWJ |

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|--------------------|-----------------------|---|----------------|
| /JH/ | NPL-1 | BAUMGARTNER, I., et al., "Constitutive Expression of pHVEGF ₁₆₅ After Intramuscular Gene Transfer Promotes Collateral Vessel Development in Patients With Critical Limb Ischemia," <i>Circulation</i> 97:1114-1123, Lippincott, Williams, & Wilkins (1998) | |
| | NPL-2 | CHEN, Z-Y., et al., "Linear DNAs Concatemerize <i>in Vivo</i> and Result in Sustained Transgene Expression in Mouse Liver," <i>Mol. Ther.</i> 3:403-410, Academic Press (March 2001) | |
| | NPL-3 | CHENG, S.H., and Scheule, R.K., "Airway delivery of cationic lipid: DNA complexes for cystic fibrosis," <i>Adv. Drug Deliv. Rev.</i> 30:173-184, Elsevier Science B.V. (1998) | |
| | NPL-4 | CHERNG, J.-Y., et al., "Effect of DNA topology on the transfection efficiency of poly(2-dimethylamino)ethyl methacrylate)-plasmid complexes," <i>J. Control. Release</i> 60:343-353, Elsevier Science B.V. (1999) | |
| | NPL-5 | DALESANDRO, J., et al., "Gene Therapy for Donor Hearts: Ex Vivo Liposome-Mediated Transfection," <i>J. Thorac. Cardiovasc. Surg.</i> 111:416-422, Mosby-Year Book, Inc. (1996) | |
| | NPL-6 | DANKO, I., et al., "Dystrophin expression improves myofiber survival in <i>mdx</i> muscle following intramuscular plasmid DNA injection," <i>Hum. Mol. Genet.</i> 2:2055-2061, Oxford University Press (1993) | |
| | NPL-7 | DARQUET, A-M., et al., "A new DNA vehicle for nonviral gene delivery: supercoiled minicircle," <i>Gene Ther.</i> 4:1341-1349, Nature Publishing Group (1997) | |
| | NPL-8 | DAVIS, H.L., et al., "Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen," <i>Vaccine</i> 12:1503-1509, Butterworth-Heinemann Ltd. (1994) | |
| | NPL-9 | DOW, S.W., et al., "Systemic and Local Interferon γ Gene Delivery to the Lungs for Treatment of Allergen-Induced Airway Hyperresponsiveness in Mice," <i>Hum. Gene Ther.</i> 10:1905-1914, Mary Ann Liebert, Inc. (1999) | |
| ↓ | NPL-10 | GRAMZINSKI, R., et al., "Immune Response to a Hepatitis B DNA Vaccine in <i>Atos</i> Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Mol. Med.</i> 4:109-118, The Picower Institute Press (1998) | |

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| Sheet | 2 | of | 3 | Attorney Docket Number | 1530.0620001/EJH/UWJ |

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| /JH/ | NPL-11 | HARLAND, R., and Mishler, L., "Stability of RNA in developing <i>Xenopus</i> embryos and identification of a destabilizing sequence in TFIIB messenger RNA," <i>Development</i> 102:837-852, The Company of Biologists Limited (1988) | |
| | NPL-12 | HORTON, H.M., <i>et al.</i> , "A gene therapy for cancer using intramuscular injection of plasmid DNA encoding interferon α ," <i>Proc. Natl. Acad. Sci. USA</i> 96:1553-1558, National Academy of Sciences (1999) | |
| | NPL-13 | LEVY, M.Y., <i>et al.</i> , "Characterization of plasmid DNA transfer into mouse skeletal muscle: evaluation of uptake mechanism, expression and secretion of gene products into blood," <i>Gene Ther.</i> 3:201-211, Nature Publishing Group (1996) | |
| | NPL-14 | MIR, L.M., <i>et al.</i> , "High-efficiency gene transfer into skeletal muscle mediated by electric pulses," <i>Proc. Natl. Acad. Sci. USA</i> 96:4262-4267, National Academy of Sciences (1999) | |
| | NPL-15 | MOFFATT, M., and Cookson, W., "Naked DNA: New shots for allergy?," <i>Nat. Med.</i> 2:515-516, Nature America Inc. (1996) | |
| | NPL-16 | NOVO, F.J., <i>et al.</i> , "Gene transfer and expression of human α -galactosidase from mouse muscle in vitro and in vivo," <i>Gene Ther.</i> 4:488-492, Nature Publishing Group (1997) | |
| | NPL-17 | PELLETIER, J., and Sonenberg, N., "Internal initiation of translation of eukaryotic mRNA directed by a sequence derived from poliovirus RNA," <i>Nature</i> 334:320-325, Macmillan Magazines Ltd. (1988) | |
| | NPL-18 | PICCIRILLO, C.A., and Prud'homme, G.J., "Prevention of Experimental Allergic Encephalomyelitis by Intramuscular Gene Transfer with Cytokine-Encoding Plasmid Vectors," <i>Hum. Gene Ther.</i> 10:1915-1922, Mary Ann Liebert, Inc. (1999) | |
| | NPL-19 | PICCIRILLO, C.A., <i>et al.</i> , "TGF- β 1 Somatic Gene Therapy Prevents Autoimmune Disease in Nonobese Diabetic Mice," <i>J. Immunol.</i> 161:3950-3956, The American Association of Immunologists (1998) | |
| | NPL-20 | QIN, L., <i>et al.</i> , "Gene Transfer for Transplantation - Prolongation of Allograft Survival with Transforming Growth Factor- β 1," <i>Ann. Surg.</i> 220:508-519, J.B. Lippincott Company (1994) | |

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| /JH/ | NPL-21 | QIN, Y.-J., <i>et al.</i> , "Gene Suture - A Novel Method for Intramuscular Gene Transfer and its Application in Hypertension Therapy," <i>Life Sci.</i> 65:2193-2203, Elsevier Science Inc. (1999) | | | |
| | NPL-22 | RAGNO, S., <i>et al.</i> , "Protection of Rats from Adjuvant Arthritis by Immunization with Naked DNA Encoding for Mycobacterial Heat Shock Protein 65," <i>Arthritis Rheum.</i> 40:277-283, American College of Rheumatology (1997) | | | |
| | NPL-23 | RESTIFO, N.P., <i>et al.</i> , "Enhancing the Recognition of Tumour Associated Antigens," <i>Folia Biologica</i> 40:74-88, Institute of Molecular Genetics (1994) | | | |
| | NPL-24 | SCHRIJVER, R.S., <i>et al.</i> , "Immunization of cattle with a BHV1 vector vaccine or a DNA vaccine both coding for the G protein of BRSV," <i>Vaccine</i> 15:1908-1916, Elsevier Science Ltd. (1997) | | | |
| | NPL-25 | TRIPATHY, S.K., <i>et al.</i> , "Long-term expression of erythropoietin in the systemic circulation of mice after intramuscular injection of a plasmid DNA vector," <i>Proc. Natl. Acad. Sci. USA</i> 93:10876-10880, National Academy of Sciences (1996) | | | |
| | NPL-26 | TSURUMI, Y., <i>et al.</i> , "Direct Intramuscular Gene Transfer of Naked DNA Encoding Vascular Endothelial Growth Factor Augments Collateral Development and Tissue Perfusion," <i>Circulation</i> 94:3281-3290, Lippincott, Williams, & Wilkins (1996) | | | |
| | NPL-27 | ULMER, J.B., <i>et al.</i> , "Immunization Against Viral Proteins with Naked DNA," <i>Ann. N.Y. Acad. Sci.</i> 772:117-125, New York Academy of Sciences (1995) | | | |
| | NPL-28 | VAHLSING, H.L., <i>et al.</i> , "Immunization with plasmid DNA using a pneumatic gun," <i>J. Immunol. Methods</i> 175:11-22, Elsevier Science B.V. (1994) | | | |
| ↓ | NPL-29 | YAGI, K., <i>et al.</i> , "Basic Study on Gene Therapy of Human Malignant Glioma by Use of the Cationic Multilamellar Liposome-Entrapped Human Interferon β Gene," <i>Hum. Gene Ther.</i> 10:1975-1982, Mary Ann Liebert, Inc. (1999) | | | |
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